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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,914

09/29/2006

Oumeima Ben Youssef

9052.250

4613

20792 7590 03/27/2008
MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER

TREYGER, ILYA Y

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

03/27/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,914	Applicant(s) BEN YOUSSEF, OUMEIMA	
	Examiner ILYA Y. TREYGER	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, and 15-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant amended claim 1.
2. Claim 14 is canceled.
3. Claims 1-13 and new claims 15-20 of U. S. Application 11/360,850 filed 02/23/2006, are examined on the merits.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

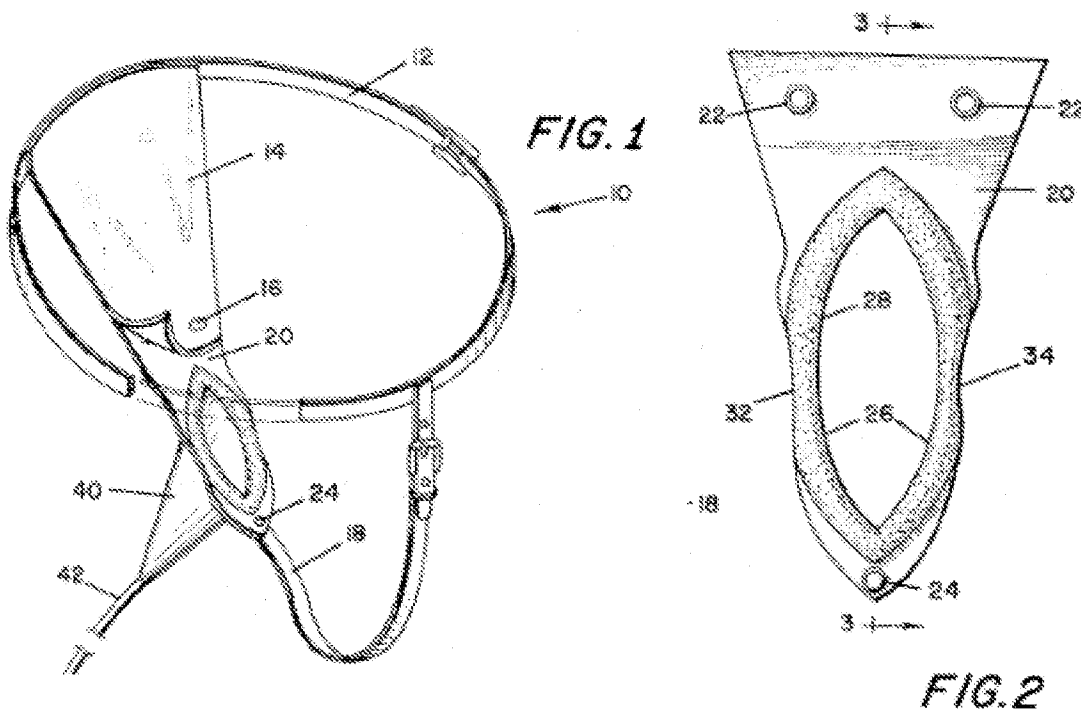
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 8, 10, 12, 13, and 15-20 are rejected under 35 U.S.C. 102(b) as anticipated by MAYHORN (US 3,374,790).
6. In Re claim 1, MAYHORN discloses a non-intrusive female urinary incontinence device comprising a flexible elastic substantially flat strip 18, 20 (Figs. 1, 2) having a flat upper face and a lower face, an opening 26 (Fig. 2) being provided in the strip communicating between the upper and lower faces, a fluid collection means surrounding 28 (Fig. 2) the opening in a fluid tight manner on the lower face of the strip and means 24 for attaching the device to a supporting means (18), wherein the strip and opening are sized and shaped such that when it is stretch fitted over the external urogenital organs the labia minora extends through the opening and a fluid tight fit between the upper face of the strip and the flesh surrounding the labia minora and around the

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base of the labia minora is fowled, such that in use urine is conveyed from the urethra, through the labia minora, into the collection means without leakage (See Figs. 1 and 2).

Since the strap 18, 20 and the pad 28 have been made of flexible material (Col. 2, ln. 23-25), one skilled in the art can clearly envisaged that the flexible strip terminates against flesh residing outside the labia minora and inside the labia maiora and wherein the flat upper face of the strip conforms to the shape of the wearer and defines a fluid tight fit between the upper face of the strip and the flesh surrounding the labia minora and around the base of the labia minora. It is further noted that the anatomical features are specific and different for each female, and therefore, the flexibility of the materials used in Mayhorn makes the device fully capable of being adjusted according to the individual features of the wearer.



7. In Re claim 2, MAYHORN discloses a device wherein the fluid collection device comprises a funnel portion (40) the curved wall of which at an upper end extends circumferentially from the surface of the oval region around the opening and curves inwards to a lower open end suitable for communicating with a collection vessel (See Fig 1).

8. In Re claim 8, MAYHORN discloses a device wherein the funnel is integral to the strip (Fig. 1).

9. In Re claim 10, MAYHORN discloses a device wherein the length of said straps is adjustable with respect to the waistband to allow for differences in size and shape of the user (See Fig. 1).

10. In Re claim 12, MAYHORN discloses a urinary incontinence device further comprising a waistband (12) and means for attachment to the device (See Fig. 1).

11. In Re claim 13, MAYHORN discloses a device wherein the attachment means is adjustable to maintain a positive tension on the device when in use (See Fig. 1).

12. In Re claim 15, MAYHORN discloses a funnel-like receiver made of pliable foldable water impervious material (Col. 2, ln. 36, 37) and consequently fully capable of being folded as claimed allowing a wearer to place underwear over the funnel.

13. In Re claim 16, MAYHORN discloses the urinary device wherein the strip 18, 20 (Fig. 1) elongates anteriorly and posteriorly to merge into extension straps and, therefore is fully capable of providing a continuous seal.

14. In Re claim 17, MAYHORN discloses a female urinary device, comprising:

a strip 18, 20 (Fig. 1) having two opposing outer perimeter segments surrounding a urine flow passage 26 (Fig. 2), the outer perimeter segments made of flexible resilient material (Col. 2,

ln. 23-25), and therefore fully capable of residing snugly against anatomical structures of the wearer as claimed and define a fluid-tight seal while allowing the labia minora to extend through the urine flow passage of the strip;

a collection funnel 40 (Fig. 1) sealable attached to the strip and in fluid communication with the urine flow passage 26 (Fig. 2); and

a securing member 12 (Fig. 1) configured to hold the strip in position on the wearer, wherein, in use, urine flows from the urethra, between the labia minora, then to the funnel in a leak-proof manner due to seal provided by pad 28 (Col. 2, ln. 67, 68; Figs. 1 and 2).

15. In Re claim 18, MAYHORN discloses the urinary device wherein the strip 18, 20 (Fig. 1) is a flat flexible strip (Fig. 1).

16. In Re claim 19, MAYHORN discloses the urinary device, comprising:

a strip 18, 20 (Fig. 1) having two opposing outer perimeter segments surrounding a urine flow passage 26 (Fig. 2), the outer perimeter segments made of flexible resilient material (Col. 2, ln. 23-25), and therefore fully capable of residing snugly against anatomical structures of the wearer as claimed and define a fluid-tight seal while allowing the labia minora to extend through the urine flow passage of the strip;

a collection funnel 40 (Fig. 1) sealable attached to the strip and in fluid communication with the urine flow passage 26 (Fig. 2); and

a securing member 12 (Fig. 1) configured to hold the strip in position on the wearer, wherein, in use, urine flows from the urethra, between the labia minora, then to the funnel in a leak-proof manner due to seal provided by pad 28 (Col. 2, ln. 67, 68; Figs. 1 and 2).

17. In Re claim 20, MAYHORN discloses the urinary device wherein the strip 18, 20 (Fig. 1) is a flat flexible strip (Fig. 1).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

20. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over MAYHORN (US 3,374,790) in view of Giacalone et al. (US 4,615,692).

MAYHORN discloses the claimed invention discussed above, but does not expressly disclose the urinary device wherein the strip portion is maintained under tension in use.

Giacalone discloses a device in which the strip portion is maintained under tension in use (See Col. 2, ln. 56-58).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the urinary device of MAYHORN with the strip

portion maintained under tension in use, as taught by Giacalone, because such modification would improve anti leakage features of the device.

21. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over MAYHORN (US 3,374,790) in view of Birbara (US 5,894,608).

MAYHORN disclose the claimed invention discussed above, but do not expressly disclose the device wherein the anterior surface of the wall of said funnel curves more sharply than the posterior surface, such that the lower opening at the base of the funnel lies in a lower plane than that of the opening in the strip.

Birbara teaches that it is known to use the anterior surface of the wall of said funnel curves more sharply than the posterior surface, such that the lower opening at the base of the funnel lies in a lower plane than that of the opening in the strip (See Fig. 1).

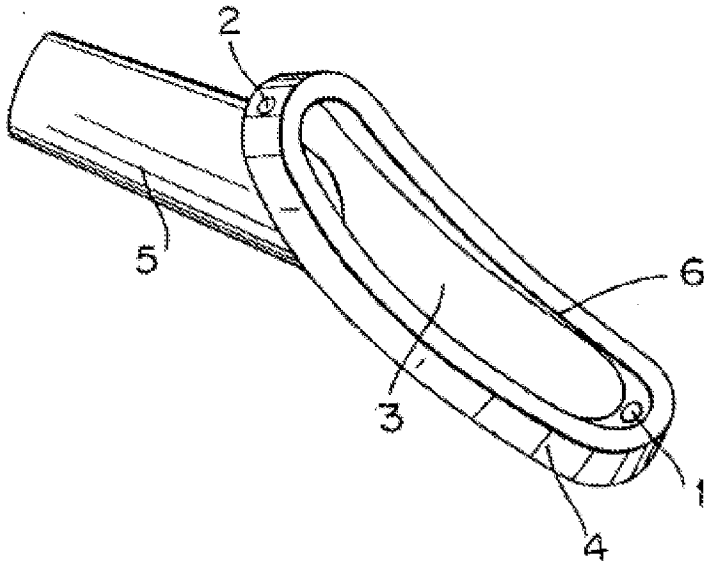


FIG. 1

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the funnel of MAYHORN with the anterior surface of the wall of said funnel curves more sharply than the posterior surface, such that the lower opening at the base of the funnel lies in a lower plane than that of the opening in the strip, as taught by Birbara because such modification would improve the hydraulic communication with a collection vessel.

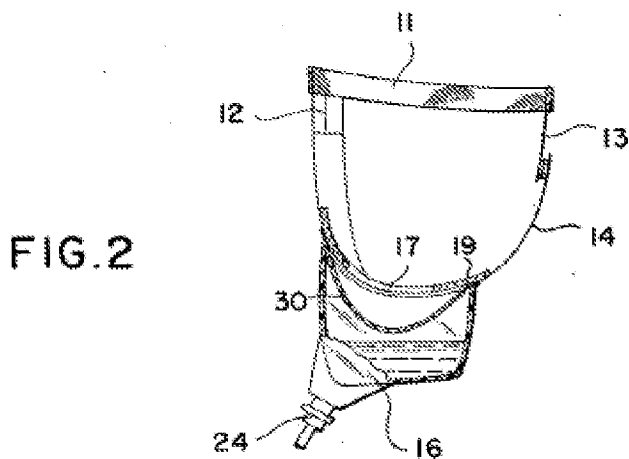
22. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over MAYHORN (US 3,374,790) in view of Bermingham (US 4,116,197).

MAYHORN disclose the claimed invention, but do not expressly disclose the funnel has a double-walled structure, the inner curved wall narrowing symmetrically and more sharply than

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the outer wall so that an internal opening is formed substantially parallel to and of smaller radius than the opening in the strip.

Birmingham teaches that it is known to use the double-walled funnel, the inner curved wall narrowing symmetrically and more sharply than the outer wall so that an internal opening is formed substantially parallel to and of smaller radius than the opening in the strip (See Col. 2, ln. 57-61; Fig. 2).



It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of MAYHORN with the double-walled funnel, as taught by Birmingham because such modification would prevent the urine from flowing back into the interior opening.

23. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over I. B.

MAYHORN (US 3,374,790) in view of Birbara (US 5,894,608), as applied to claim 3 above, and further in view of Birmingham (US 4,116,197).

24. In Re claim 5, MAYHORN in view of Birbara disclose the claimed invention discussed above, but do not expressly disclose a device wherein a cavity is formed between the posterior

surface of the inner wall and the posterior surface of the outer wall such that, when the user is in a horizontal position, urine which has passed through the internal opening of the funnel is prevented from flowing back into the cavity between said opening and the oval opening of the strip.

Bermingham teaches that it is known to use a cavity is formed between the posterior surface of the inner wall and the posterior surface of the outer wall such that, when the user is in a horizontal position, urine which has passed through the internal opening of the hel is prevented from flowing back into the cavity between said opening and the oval opening of the strip (See Col. 2, ln. 57-61; Fig. 2).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of MAYHORN in view of Birbara with the a cavity is formed between the posterior surface of the inner wall and the posterior surface of the outer wall such that, when the user is in a horizontal position, urine which has passed through the internal opening of the hel is prevented from flowing back into the cavity between said opening and the oval opening of the strip, as taught by Bermingham because such modification would prevent the urine from flowing back into the interior opening.

25. In Re claim 6, Bermingham discloses the device wherein the inner wall and outer wall are spaced apart such that urine in the cavity is prevented from flowing back into the interior opening ((See Col. 2, ln. 57-61; Fig. 2).

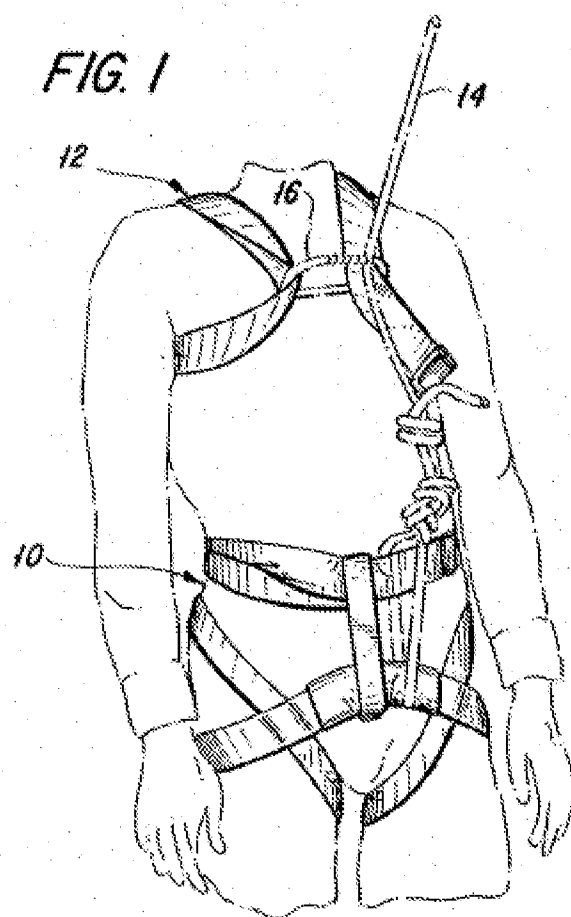
26. In Re claim 7, MAYHORN discloses a device wherein the exterior wall of the funnel is constructed of resilient flexible material (See Col. 1, ln. 8-10), but does not expressly disclose the interior wall constructed with substantially the same material as the strip.

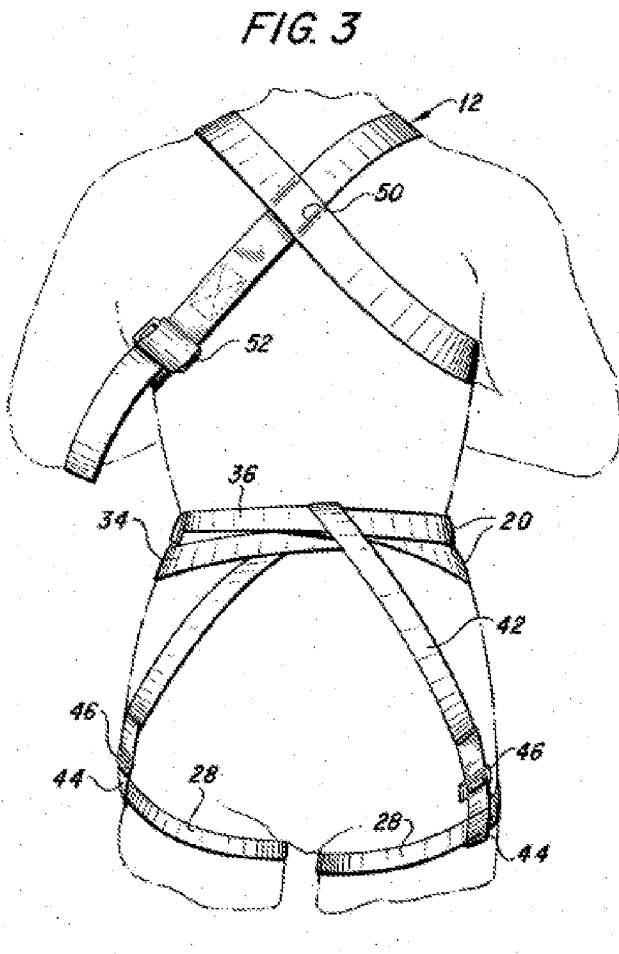
It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the interior wall substantially the same material as the strip, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

27. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over MAYHORN (US 3,374,790) in view of Markwell et al. (US 4,632,217).

MAYHORN disclose the claimed invention, but do not expressly disclose the strip comprises divergent elongated straps at the front and rear to provide anterior and posterior support straps for attachment to a supporting waistband, so that in use the strip is stretched tightly over the external urogenital organs.

Markwell teaches that it is known to use a support system comprising of the strip comprises divergent elongated straps at the front and rear to provide anterior and posterior support straps for attachment to a supporting waistband (See Figs. 1 and 2).





It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of MAYHORN with the strip comprises divergent elongated straps at the front and rear to provide anterior and posterior support straps for attachment to a supporting waistband, as taught by Markwell because such modification would improve the maintenance of the positive tension on the device when in use.

Response to Arguments

28. Applicant argues that Mayhorn proposes a device where the collection cup resides over and outside the labia majora and the outside edges of the pad actually contact the legs of the user.

However since the strap 18, 20 and the pad 28 have been made of flexible material (Col. 2, ln. 23-25), one skilled in the art can clearly envisaged that the flexible strip terminates against flesh residing outside the labia minora and inside the labia maiora and wherein the flat upper face of the strip conforms to the shape of the wearer and defines a fluid tight fit between the upper face of the strip and the flesh surrounding the labia minora and around the base of the labia minora. It is further noted that the anatomical features are specific and different for each female, and therefore, the flexibility of the materials used in Mayhorn makes the device fully capable of being adjusted according to the individual features of the wearer.

29. Applicant further argues that Mayhorn proposes a relatively thick foamed plastic pad 28 with increasing thickness along one direction, from 0.25 inches at one end to one inch at the other end (col. 2, lines 30-31). Applicant submits that in the device proposed by Mayhorn, leakage can occur, especially at the posterior end of the pad.

However since Applicant has neither claimed nor disclosed any dimensions and has never provided a factual evidence that the device of Mayhorn can leak, such argument is not persuasive.

Conclusion

29. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Ilya Treyger
Examiner
AU 3761

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761